

### **REMARKS/ARGUMENTS**

Applicant would like to thank the Examiner for the careful consideration given the present application. The application has been carefully reviewed in light of the Office Action, and amended as deemed appropriate to place the application into condition for allowance.

Specifically, by this amendment claims 1-10 have been cancelled. No claims have been amended and no new claims have been added to the application. Accordingly, claims 13-18 are pending in the application. No new matter has been added.

In the prior Office Action, the Examiner rejected claims 1-4, 6-10, 13 and 15-18 under 35 U.S.C. §102(b) as being anticipated by Nielsen et al. (U.S. Pat. No. 5,716,558) as evidenced by Engelsberg (U.S. Pat. No. 5,821,175). As noted above, claims 1-4 and 6-10 have been canceled from the application thereby rendering the prior rejection thereof moot. For the reasons set forth below, applicant respectfully requests reconsideration of the rejection of claims 13 and 15-18 under 35 U.S.C. §102(b).

Nielsen et al. discloses a method for producing coating powders, catalysts and drier water-borne coatings by spraying compositions with compressed fluids (see Abstract). Every embodiment of the invention disclosed in Nielsen et al. includes a step consisting of **spraying a liquid mixture** at a temperature and pressure that gives a substantially decompressive spray by passing the mixture **through an orifice** into an environment suitable for forming solid particulates by solvent evaporation (see col. 2, lines 13-18; col. 2, lines 57-60; col. 3, lines 33-36; col. 4, lines 1-5; and col. 4, lines 22-26). The Nielsen et al. process clearly does not anticipate that which is claimed in claims 13-18 of the present application.

In contrast to Nielsen et al., claim 13 claims (bold emphasis added):

A method of producing particles comprising the steps of:  
providing a load stock comprising:  
    an excipient that is a solid at 25° C. and 1 atmosphere  
        pressure; and  
    optionally, a biologically active substance;

contacting the load stock with a supercritical fluid in a pressure vessel to form a melt;  
**releasing the pressure within the pressure vessel to transform the melt into a solid porous mass** that is cooled to a temperature below 25° C.; **and**  
**milling the solid porous mass to obtain solid particles.**

It is well-settled that a claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference. See *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987). Nielsen et al. does not disclose releasing the pressure within a pressure vessel containing a melt so as to form a solid porous mass, and then milling the solid porous mass to obtain solid particles. In every embodiment, Nielsen et al. discloses spraying a liquid mixture through an orifice into an environment where solid particulates are formed by solvent evaporation. This is an entirely different process, and the Examiner's rejection of claims 13 and 15-18 as being anticipated by Nielsen et al. is clearly improper and should be withdrawn.

Also in the prior Office Action, the Examiner rejected claims 5 and 14 under 35 U.S.C. §103(a) as being unpatentable over Nielsen et al. as evidenced by Engelsberg. As noted above, claim 5 has been canceled thereby rendering the prior rejection thereof moot. However, applicant respectfully submits that claim 14 is clearly patentable over Nielsen et al. as evidenced by Engelsberg. Reconsideration is thus respectfully requested.

Claim 14 depends from claim 13 and is patentable over Nielsen et al. as evidenced by Engelsberg for the same reasons that claim 13 is clearly patentable over such references. Neither Nielsen et al. nor Engelsberg fairly teach or suggest milling a solid porous mass before the temperature of the solid porous mass is permitted to rise to or above 25° C. And such a method step would not have been obvious to one as a matter of routine optimization, particularly when the prior art reference relied upon teaches the formation of particles by a spray evaporation process.

In light of the foregoing, it is respectfully submitted that the present application is in a condition for allowance and notice to that effect is hereby requested. If it is

determined that the application is not in a condition for allowance, the Examiner is invited to initiate a telephone interview with the undersigned attorney to expedite prosecution of the present application.

If there are any additional fees resulting from this communication, please charge same to our Deposit Account No. 18-0160, our Order No. FER-14670.001.002.

Respectfully submitted,

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